

# Privacy and Confidentiality

Abstracts 29, 42, 67, 68, 69

## Two Regional Registries Approach to Consent; Lessons Learned

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**Key Words:** Consent. Privacy. Confidentiality

**Background:** The implementation of the NYS Immunization Information System consisted of the development of four regional immunization registries. No legislation was enacted at the state level to mandate participation or develop policies for the regions. Each registry was to create an Immunization Registry that would meet the needs of the region it was to serve. Therefore many of the business rules developed, such as the role of consent, vary across the regions.

**Objective:** To present two regional approaches to the role of consent in their population-based registries.

**Methods:** Comparisons were made of the development of notice and consent in each region. An analysis of the strengths and weaknesses of the business rules for each model was also completed.

**Results:** A review of the actual consent has shown that there is basic agreement on what should be covered in the consent. The notice rules, however, differ significantly between regions. Each process has distinct strengths and weaknesses. To date, though, no clear model has emerged as the better approach.

**Conclusions:** Consent and Notice are critical policies that must be determined prior to the implementation of a registry and be frequently reevaluated. It is important to not only develop a process that can work in the current environment but also in the future. Additionally, concerns about how consent is implemented will vary from group to group. Who is at the decision making table will affect the process.

**Learning Objective:** To understand how different models of consent and notice will effect an Immunization Registry.

## The Impact of HIPAA Privacy and Security Rules on Immunization Registries

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**Key Words:** HIPAA, Privacy, Security

**Background:** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires Congress to enact federal privacy legislation by August 1996 or the Secretary of the Department of Health and Human Services is to promulgate regulations. HIPAA also requires the Secretary to promulgate rules for the security of certain information that is maintained and transmitted electronically. Since Congress did not enact privacy legislation by August 1996, privacy and confidentiality rules that will impact immunization registries have been published.

**Objective:** To present the relevant portions of the privacy and security rules and discuss the potential impact of the rules on immunization registries.

**Methods:** Proposed and final rules for privacy and security were reviewed and analyzed to assess the potential impact of the rules on immunization registries.

**Results:** The scope of the security rule is broader than the scope of the privacy rule.

**Results:** Security rules will impact all immunization registries. Privacy rules will impact health care providers, including state and local health departments that provide direct service. It is important for all immunization registry developers and managers to understand the potential impact of these rules on registries.

**Learning Objective:** Participants will learn about the final rules for privacy and security that are required by HIPAA, and understand the potential impact of the rules on immunization registries.

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## Confidentiality and Privacy Issues in Consent-Based Registries

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**Key Words:** Confidentiality. Consent. HIPAA. Law. Legislation. Parent concerns. Privacy.

**Background:** A major issue consent-based registries face concerns confidentiality and the privacy of the medical data. Illinois has been able to develop a registry that, while consent-based, protects confidential data. New legislation and HIPAA regulations, however, also ensure that confidentiality issues will need to be addressed in the future.

**Objective:** To explain the major confidentiality issues, how to incorporate them into registries, and to discuss changing regulations and legislation to lawyers, non-lawyers, registry designers, technical staff, administrators, and all support staff.

**Methods:** Review confidentiality and privacy rules and statutes and how they have been incorporated into registry applications. Review current legislation and federal rulemakings that will affect consent-based registries in the future.

**Results:** Several steps have been taken to ensure confidentiality is protected in the Illinois registry, thereby maximizing the utility of the registry and also the confidence that concerned individuals will have about the privacy of their medical data.

**Conclusions:** Issues of confidentiality do not preclude an effective registry, but must be addressed in the philosophy and design of the registry. Privacy and utility must be considered together to balance all concerns and promote a user-friendly registry.

**Learning Objective:** Non-lawyer participants will understand major issues of confidentiality, including HIPAA and also understand current rulemaking and legislation issues concerning privacy of healthcare information. Participants will also describe how to incorporate these concerns and new laws into effective registry design and implementation.

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## Minimum Specifications for Protecting Privacy and Confidentiality in Immunization Registries

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**Key Words:** Privacy. Confidentiality. Immunization Registries

**Background:** In response to President Clinton's 1997 directive to Secretary Shalala to work with the states on the development of an integrated immunization registry system, an Initiative on Immunization Registries was undertaken by the National Vaccine Advisory Committee (NVAC) with support from the CDC and the National Vaccine Program Office. Four public hearings were held and over 100 experts provided testimony on key issues including privacy and confidentiality. In January 1999, NVAC approved a report entitled "Development of Community- and State-Based Immunization Registries" that recommends the development of minimum specifications for protecting and confidentiality in immunization registries. A CDC-led team developed minimum specifications based on the NVAC recommendations and the experience of registry developers and managers in the public and private sector. The updated Community Immunizations Registries Manual chapter on Confidentiality contains these minimum specifications and guidelines for implementing the specifications in a manner that is consistent with the community values of the population served by the registry.

**Objective:** To describe the minimum specifications for protecting the privacy of registry participants and the confidentiality of information contained in registries, and to discuss the process and challenges involved in implementing the specifications.

**Methods:** Minimum specifications for confidentiality policies and agreements, notice, choice, access, disclosure, and use of information, penalties, and data retention will be reviewed, as well as some guidelines for implementing the minimum specifications.

**Results:** The updated Community Immunization Registries Manual chapter on Confidentiality incorporates the current views and experience of immunization registry developers and managers and experts in the public and private sector. The chapter is consistent with the NVAC recommendations and national level privacy legislation and regulations.

**Conclusions:** Registry developers and managers have expressed the need for guidance regarding the protection of privacy and confidentiality. Minimum specifications will help ensure the privacy of registry participants and the confidentiality of information contained in registries.

**Learning Objective:** Participants will learn about the minimum specifications for protecting privacy and security in immunization registries, and the process for implementing the specifications.

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## Increasing Access to Immunization Records While Protecting Privacy and Confidentiality in California

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**Key Words:** Legislation. Privacy/Confidentiality. Partnerships. WIC. Schools. Health plans

**Background:** California legislation authorized local health officers to operate a registry in conjunction with the State, and for providers to give and receive immunization information pertaining to a specific child. Under this legislation providers are required to inform parents of their intent to share immunization information with a registry, and allow them to refuse. Sharing of this information with other partners such as schools, child care centers, WIC programs or health plans was not permitted, though two-thirds of California's birth cohort is eligible for WIC program services.

**Objective:** To describe the process to allow the sharing of immunization data with important public health partners; how this affected the disclosure process and operation of a registry, and new issues that have emerged.

**Methods:** Review the history and status of registry related legislation; the legislative process to protect privacy and confidentiality while at the same time increasing access to immunization records; and describe how these changes have been implemented and new operational issues that have emerged.

**Results:** Legislation in CA was amended and enacted in 1999 to allow registries to share immunization records with schools, child care centers, WIC programs and health plans. This change requires redisclosure and technical ability to mask phone and address information from certain recipients of information. New partners need to be added, and with the changing landscape of registries in California, other issues have emerged.

**Conclusions:** California has attempted to create legislation that reflects a design for immunization registries that includes participation of all the important public health partners that are part of ensuring that children are appropriately immunized in our state. Sometimes the results cause operational difficulties and the changing health care landscape may require new cleanup legislation.

**Learning Objectives:** Understand issues involved in sharing immunization information with non-health care provider organizations, demonstrate legislative decisions and strategies and how they can affect operations of a registry.